#### **PATENT**

Inventor: G	RAY	)	
For: LIMI	B FOR BREATHING CUIT	( )	hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
Serial No.:	10/653,821	)	December 12,2003
Filed:	September 3, 2003	)	Tottiny E. Station
Art Unit:	3764	) _	- :
Atty Docket No · 1171/41357/134			· •

#### TRANSMITTAL OF CERTIFIED COPY **REGARDING CONVENTION CLAIM UNDER 35 U.S.C. §119**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In completion of Applicant's claim for priority under 35 U.S.C. §119 for United States Patent application, please find enclosed a true copy of the patent application as filed on 09 September 2002 with an application for Letters Patent number 521274.

It is believed that this completes Applicant's claim for priority and acknowledgment of receipt of this priority document is requested.

Respectfully submitted,

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## CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 9 September 2002 with an application for Letters Patent number 521274 made by FISHER & PAYKEL HEALTHCARE LIMITED.

Dated 17 September 2003.

**Neville Harris** 

Commissioner of Patents, Trade Marks and

**Designs** 



# NEW ZEALAND PATENTS ACT, 1953

PROVISIONAL SPECIFICATION

Limb for Breathing Circuit

We, FISHER & PAYKEL HEALTHCARE LIMITED, a company duly incorporated under the laws of New Zealand of 15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand do hereby declare this invention to be described in the following statement:

#### **BACKGROUND TO THE INVENTION**

The present invention relates to components for breathing circuits and in particular to limbs for breathing circuits.

#### SUMMARY OF THE PRIOR ART

In assisted breathing, particularly in medical applications, gases are supplied and returned through conduits. Such conduits are ideally light and flexible to ensure the greatest level of comfort for the patient.

As taught in our prior patent application AU 43823/01 thin membrane walls are particularly used in breathable membrane applications where the passage of water vapour through the membrane but not the passage of liquid water is desired.

Thin walled conduits may include helical or annular reinforcing ribs which improve resistance to crushing and pinching, while still allowing the conduit to be flexible. A disadvantage of these types of flexible conduits is their lack of stiffness. The extremely thin walls of these types of conduits provide very little resistance to tensile, compressive or torsional forces. While annular or helical ribs, whether inside, outside or between layers of the conduit wall, do provide some longitudinal stiffness, these conduits are still prone to large axial displacements both compressive and tensile. This can lead to substantial internal volume changes under fluctuating breathing pressures, sometimes significant enough to disrupt automated ventilation. Our prior art patent application taught provision of external longitudinal reinforcing in the form of a set of axial polymer threads bonded to the radial support bead. However these have the disadvantage of being easily caught or snagged.

A further disadvantage of very thin walled conduits is a reduced durability of the very thin membrane making up the walls of the conduit. The very thin membrane may be more susceptible to piercing from sharp objects and/or plastic deformation from tensile forces.

#### SUMMARY OF THE INVENTION

It is an object of the present invention to provide a limb for a breathing circuit, which will at least go some way towards improving on the above or which will at least provide the public and the medical profession with a useful choice.

Throughout this specification very thin walled conduits shall refer to a conduit where under the intended prevailing conditions the conduit would be subject to excessive axial compression, e.g. a conduit formed according to US 3,910,808 using a SYMPATEX film having a thickness less than 50 microns.

In one aspect the invention consists in a limb for a breathing circuit comprising: a very thin walled conduit having a first end and a second end and a breathing gases pathway therebetween,

- a first connector fixed to said first end of said conduit,
- a second connector fixed to said second end of said conduit, and

a spine within said very thin walled conduit and connected with said first connector and said second connector.

Preferably said connectors have a first end suitable for making connection with auxiliary equipment and a second end for making connection with a breathing conduit, and

an annular shoulder between said first end and said second end,

said second end extending along an axis and having a substantially circular cross section, and

said second end having at least one protrusion on an outer surface for interlocking engagement with a helical rib of a breathing conduit.

Preferably said protrusion is an external thread having a pitch suitable for engagement with said helical rib of a breathing conduit.

Preferably said shoulder portion has an annular recess for receiving a securing collar having an extrusion axis.

Preferably said second end of said end connector has a recess substantially parallel with said axis for receiving said spine.

Preferably said securing collar has a recess substantially parallel with said extrusion axis for receiving said spine.

Preferably said spine has two ends, and a substantially circular cross section.

Preferably said spine is solid, but said spine may also be hollow, in which case said hollow spine may be blind terminated at each end by said end connector.

Preferably said hollow spine is too small to be a conduit for gases delivery, but could be large enough to be used as a pressure measurement conduit.

Preferably said spine has a cross sectional area less than 10% of the cross sectional area of the bore of said breathing conduit.

Said spine may include a positive temperature coefficient heating element or a resistance heating element.

Preferably said spine is substantially the same length as said conduit and follows a non-tortuous path between said connectors.

In a further aspect the invention consists in a method for manufacturing a limb for a breathing circuit comprising:

providing a breathing conduit having a first end and a second end,

locating a spine having a first and a second end, inside said breathing conduit,

fixing a first end connector with a first end of said breathing conduit, and a first end of said spine, and

fixing a second end connector with said second end of said conduit and said second

end of said spine.

In a further aspect the invention may broadly be said to consist in a limb for a breathing circuit comprising:

- a very thin walled conduit having a first end and a second end,
- a first connector fixed to said first end of said conduit,
- a second connector fixed to a second end of said conduit, and
- a braided sheath surrounding said conduit and being fixed at and around one end to said first connector and at and around its other end to said second connector.

Preferably said mesh is a braided tube braided from polyethylene terephthalate monofilaments.

In a further aspect the invention consists in a method for manufacturing a limb for a breathing circuit comprising:

providing a breathing conduit having a first end and a second end,

locating a reinforcing mesh having a first and a second end, over the outside of said breathing conduit,

fixing a first end connector with a first end of said breathing conduit, and a first end of said reinforcing mesh, and

fixing a second end connector with said second end of said conduit and said second end of said reinforcing mesh.

To those skilled in the art to which the invention relates, many changes in construction and widely differing embodiments and applications of the invention will suggest themselves without departing from the scope of the invention as defined in the appended claims. The disclosures and the descriptions herein are purely illustrative and are not intended to be in any sense limiting.

### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a cross sectional side elevation of a single walled breathing conduit formed by applying a molten reinforcing bead on top of overlapping spirally wound thin film layers.

Figure 2 is a cross sectional side elevation of a double walled breathing conduit formed in a manner analogous to the conduit shown in Figure 1.

Figure 3 is a plan view of a conduit forming device for forming the conduit depicted in Figure 2.

Figure 4 is a cross sectional side elevation of a single walled breathing conduit formed by applying a molten reinforcing bead between the overlapping spirally wound thin film layers.

Figure 5 is a plan view of a conduit forming device for forming the conduit depicted in Figure 4.

Figure 6 is an assembly perspective view of one end of a breathing limb according to a preferred embodiment of the present invention.

Figure 7 is a partially assembled perspective view of one end of a breathing limb according to a preferred embodiment of the present invention.

Figure 8 is a cross-sectional elevation of a breathing limb according to Figure 6 and 7.

Figure 9 is an assembly perspective view of one end of a breathing limb according to a further preferred embodiment of the present invention.

Figure 10 is a cross-sectional elevation of a breathing limb according to a further preferred embodiment of the present invention.

Figure 11 is a partially assembled perspective view of one end of a breathing limb according to the present invention including an outer reinforcing mesh.

#### **DETAILED DESCRIPTION**

The present invention relates to breathing conduits in general and in particular to methods of providing reinforcement for very thin walled conduits. Consequently the present invention finds application in breathing conduits fabricated from a variety of different materials and manufactured by a variety of different methods. The conduits may be single or multiple walled and may include breathable walls or portions of breathable wall.

As a corollary of material cost and/or breathability of the material it is preferred that the conduit wall be manufactured to have a very thin wall, so much so that the conduit wall membrane may be insufficiently sturdy to be self supporting. Spiral or helical or annular reinforcing members may be provided on the tubular membrane to provide support against crushing and pinching. The helical, spiral or annular supporting members may for example be formed from polymer plastic materials, such as the material used in the wall of the conduit. It has been found that breathing conduits such as those described above are extremely light, flexible and provide good crush resistance, however the conduits may also have reduced resistance to axial deformation. Due to the very thin polymer film forming the walls of the conduit the resulting breathing circuit limb may have reduced axial stiffness and may be prone to expansion, and contraction along the axis of the conduit due to axial or torsional forces. In use axial forces arising from patient breathing may produce expansion and/or contraction along the length of the limb. The present invention provides a breathing circuit limb with improved axial and/or torsional stiffness.

Very thin walled breathing conduits such as those described above can be fabricated by a number of different methods. The following describes several very thin walled conduits and associated methods of manufacturing very thin walled conduits to which the present invention may be applied.

Referring to Figure 1 a cross section of a breathing circuit limb is shown in which the flexible wall of the conduit is formed from a very thin film plastic membrane, and wound helically with edges of adjacent turns welded together by a reinforcing bead. Supplied as tape, either pre-formed or extruded online, the very thin film is wound helically onto a former with adjacent edges of tape overlapping. A helical supporting rib, provided in a molten state is then laid on top of the overlap between adjacent turns. The helical supporting rib thermally and mechanically bonds the two adjacent strips with the

rib forming a flexible resilient conduit once cooled. The resulting product is a single walled breathing conduit which is light and flexible. Further embodiments of conduits formed by such a process, such as multiple walled conduits, can be formed by adding further stages to the above described forming process.

Referring to Figure 2 a double walled conduit may be formed by adding an additional thin film layer and supporting rib.

An example of forming apparatus suitable for manufacturing the double walled breathing tube product according to the embodiment described in Figure 2 is shown in Figure 3. The apparatus includes a former 1 preferably of a known type including a plurality of rotating rods arranged around a central support rod. The rods extend from and are rotated by a gearbox within a machine stock 2. At least in the tube forming region the rotating rods follow a helical path. The pitch angle of the rods relative to the support rod controls the pitch angle of the tube being formed. An example of such a machine is a spiral pipeline mandrel available from OLMAS SRL of Italy. Tube being formed on the former is rotated and advanced in the direction of arrow 3 by the movement of the rotating rods. The advance speed of the former is selected relative to the rotational speed so that the pitch of the helical laying of the strip or tape on to the former 1 is a little less than the width of the strip so that adjacent turns narrowly overlap. A first extruder 4 extrudes a very thin tape 5 of breathable polymer materials. The tape 5 deposits on the former 1 in a helical fashion by action of the former. The pitch of the helical disposition of tape 5 is slightly less than the width of tape 5. The helical deposition of tape 5 forms the inner breathable wall 6 of the conduit. A second extruder 7 extrudes a bead 8 of polymer material. The bead 8 deposits on the former over the joint or overlap between adjacent turns of tape 5 forming a raised bead 9 along this join and welding the overlapping turns of tape 5. A third extruder 10 extrudes a second tape 11 of breathable polymer. The second tape 11 of breathable polymer is deposited on the former 1 to span between adjacent turns of bead 8. Adjacent turns of tape 11 overlap, forming outer breathable sheath 12. A fourth extruder 13 extrudes a second molten polymer bead 14. The bead 14

is helically deposited along the overlap between adjacent turns of the second tape 11 and welds the overlapping turns of tape 11. In addition to the bonding of the film overlap by application of the molten bead other active fusing techniques may be applied.

The resulting product is a double walled reinforced breathing conduit with a space between the inner and outer walls. The breathing conduit of Figure 2 is manufactured by a method analogous to the method employed to manufacture the conduit of Figure 1. The forming apparatus shown in Figure 3 is effectively made up of two identical stages arranged in series.

The first stage of the former shown in Figure 3 consists of film extruder 4 and bead extruder 7. Film 4 is wound around former 1 while extruder 7 extrudes a molten bead on top of the overlapping layers of film 5, resulting in a conduit such as that shown in Figure 1. The second stage consists of film extruder 10 and bead extruder 13. This second stage effectively repeats the first stage over top of the conduit formed by the first stage and results in the double walled breathing conduit of Figure 2.

Referring to Figure 4, a conduit is shown according to another preferred method of manufacture of single walled breathing conduits. An example of forming apparatus suitable for manufacturing the breathing tube according to an embodiment of the present invention described in Figure 4 is shown in Figure 5. The apparatus includes a former 15 including a plurality of rotating rods arranged around a central support rod. The rods extend from and are rotated by a gearbox within a machine stock 16. At least in the tube forming region the rotating rods follow a helical path. The pitch angle of the rods relative to the support rod controls the pitch angle of the tube being formed. An example of such a machine is a spiral pipeline mandrel available from OLMAS SRL of Italy.

Tube being formed on the former is rotated and advanced in the direction of arrow 17 by the movement of the rotating rods. The advance speed of the former is selected relative to the rotational speed so that the pitch of the helical laying of the strip or tape on to the former 15 is a little less than the width of the strip so that adjacent turns narrowly overlap. A first extruder 18 extrudes a tape 19 of very thin film polymer materials. The tape 19 deposits on the former 15 in a helical fashion by action of the former. The pitch

of the helical disposition of tape 19 is slightly less than the width of tape 19. The helical deposition of tape 19 forms the wall 20 of the conduit. A second extruder 21 extrudes a bead 22 of polymer material. The molten bead 22 deposits between the overlapping portions of adjacent winds of tape 19 and is sufficiently heated to weld to the strips of tape 19. Applying the molten bead between the overlapping layers of tape may improve the weld quality as both layers of tape that are to be welded are in physical contact with the molten bead. The quality of the surface finish for the inner surface of a breathing conduit is important, as a rough inner surface may hinder gases flow and contribute to more condensation to building up in the conduit. The above described construction technique is especially suited to conduits fabricated from very thin film. The thin film is able to conform to the shape of the raised rib of the applied molten bead 22 during fabrication. By lapping very closely onto the bead and wrapping around the bead, the very thin film maintains a smooth inner surface on the finished conduit product as shown in Figure 4.

In addition to the bonding of the film to the molten bead between adjacent over lapping layers, other active fusing techniques may be applied. Active methods may include hot air welding, hot rollers or radio frequency welding.

It will be appreciated that the above described breathing conduits and methods of manufacture are provided as examples of the type of very thin walled conduits to which the present invention may be applied. The examples have been chosen to illustrate the many possible variations. Many further variations will present themselves to those skilled in the art. While some embodiments of the present invention have been described as preferred and convey particular advantages over other embodiments many other combinations may prove commercially useful.

#### Such variations may include:

- (a) the utilisation of breathable material for the conduit walls or parts of the walls;
- (b) single walled or multiple walled conduits, with or without space between the walls may be formed by adding extra stages to the forming process;
- (c) single layer or multiple layer walls;
- (d) very thin tape may be extruded at the time of forming, or pre-formed and supplied

to former on reels;

- (e) very thin tape may be provided as a laminate having a very thin film layer and a reinforcing layer which is also permeable to water vapour;
- (f) forming process may include a secondary thermal welding process;
- (g) molten bead may interpose layers or be applied on top of two or more layers;
- (h) direct extrusion or drawing or blowing of a conduit;
- (i) forming a conduit from a very thin film with a longitudinal seam;
- (j) providing a series of annular radial support beads rather than a helical radial support bead.

The present invention may be broadly described as relating to methods of reinforcing breathing circuit limbs so as to provide increased axial or torsional stiffness, or both. The first preferred embodiment of the present invention describes the provision of an axial spine and end connector whose primary function is to improve the axial stiffness of a breathing circuit limb. The second preferred embodiment of the present invention describes an external reinforcing sheath or mesh and an end connector for use with such reinforcing in a breathing circuit limb. The reinforcing mesh is bonded to the limb at only the ends of the limb where the conduit wall inserts into the end connector. It will be appreciated from the following description that the end connectors described are suitable for use with either one, or both, of the preferred embodiments of the present invention. While each embodiment of the present invention is discussed in turn, it is in no sense meant to be limiting as the preferred embodiments may be employed separately or together.

A first preferred embodiment of a breathing limb according the present invention will now be described in detail with reference to Figures 6 to 8. The breathing limb has a conduit end connector 23, suitable for connecting a breathing conduit with a device, for example a gases humidification device or ventilator or mask. One end of end connector 23 is configured to mate with auxiliary equipment such as a ventilator or mask, while the other end is configured to extend into a breathing conduit. The cross section of the end

connector is substantially circular. Between the two ends of the end connector 23 is a shoulder region which makes the transition between the respective diameters of the connector ends.

The limb includes a spine 24 inside conduit 25. Conduit 25 is such as those described above. The conduit end connector 23 has a recess 26 adapted to receive a spine or rod 24. The spine 24, runs the length of the conduit from the connectors 23 at one end of the tube, down the inside of the conduit, and ends at another end connector at the other end of the conduit. When assembled as described in this first preferred embodiment of the present invention the combination of end connector and spine will provide the breathing conduit with additional axial stiffness, and will therefore go some way to overcoming the above described disadvantages that arise from the use of breathing conduits having extremely thin film walls. In this embodiment it is preferable to choose the reinforcing spine (material, gauge and number) to be sufficiently stiff to resist buckling under the transiently reduced internal pressures that could be expected during patient breathing and sufficiently stiff to provide improved axial stiffness to the conduit. The reinforcing spine is preferably made from any suitable approved plastic material, such as polyethylene, or the same material as the end connectors if welding of the spine and end connectors is required. In the preferred embodiment the reinforcing spine has a circular cross section to minimise any potential stress raisers. The spine may be made from a variety of materials, and may have a variety of cross sections being either solid or hollow without departing from the spirit of the present invention. If the spine is hollow and has a narrow bore, the size of the bore will be insufficient for general gases flow or gases delivery. The cross sectional area of the spine is preferably less than 10% of the cross sectional area of the bore of the conduit so that gases flow is not significantly disrupted. While the spine diameter is not large enough to facilitate significant gases flow it may be used for other purposes such as pressure measurement or the spine may include a heater element such as a PTC (Positive Temperature Coefficient) heater.

It is envisaged that there are several possible variants which may be employed to secure the reinforcing spine and/or reinforcing mesh into each of the end connectors of the breathing circuit limb. The general requirements for the end connectors are as follows.

The end connectors must provide a means for securely fastening the spine and/or reinforcing mesh so as to prevent pull out during use. Preferably the end connectors are constructed such that assembly of the components during manufacture can be achieved easily. A further consideration is that the end connector when fastened to a breathing conduit to form the finished product should be neat and tidy so as to be appealing to the eye of an end user. The following describes two alternative preferred embodiments of the present invention which satisfy the abovementioned design objectives. It will be appreciated that the portion of the end connector described which connects to equipment such as a ventilator or mask may be male, female or an androgenous type connector without departing from the present invention. Further, each end of a conduit may have the same or a different type of connector according to what type of connection is required.

Referring to Figures 6 to 8, a connector according to a preferred embodiment of the present invention is shown. In order to provide a strong bond between the conduit and the connector, a portion of the connector which receives the conduit is provided with outer raised protrusions 28 to cooperate with the helical reinforcing bead of the conduit. The protrusions 28 are arranged to cooperate with the pitch of the conduits helical reinforcing bead and preferably take the form of a continuous thread. It will however be appreciated that the protrusions may be numerous discrete bumps arranged to cooperate with the conduit reinforcing bead. The raised thread 28 takes up a position between the adjacent turns of the helical reinforcing bead 35 of the conduit. The thin wall of the conduit between the reinforcing bead is able to deform to accommodate the raised external thread of the end connector locking the components together. These features provide a mechanical connection and resistance to the conduit being pulled from the connector. As shown in Figure 6 the portion of the connector which receives the conduit is also provided with a recess or groove 26 for receiving the reinforcing spine 24. For assembly, the recess 26 provides a locating means for the reinforcing spine allowing the conduit to be threaded over the external raised thread on the receiving portion of the end connector. The reinforcing spine runs up the inside of the conduit and is received into recess 26 of the end connector. The spine then emerges from the recess 26 where an end portion 36 of the

spine 24 is folded back on itself around the outside of the conduit wall. This feature provides a mechanical interlocking of the spine around the conduit wall as well as providing an end section of the spine that is in a position to be adhesively secured to the outer surface of the conduit wall.

In one preferred embodiment a retaining sleeve 29 is fitted over the assembled components. The retaining sleeve may include a raised portion 30 as shown in Figures 6 to 8 for receiving the end portion of the spine 24 which is folded back on itself on the outside of the breathing conduit. Alternatively, referring to Figure 9 the end portion of the spine 36 may be folded so it lies between the helical reinforcing bead 35 of the conduit and the raised thread 28 of the end connector 23. The assembly is secured via a tubular retaining sleeve 31. The retaining sleeve 31 and end connector 23 may be provided with a means for initial location via a snap fit interaction between a snap fit portion 32 of the end connector 23 and the lip of retaining sleeve 31. Referring to Figure 8, a suitable adhesive such as EVA glue can then be injected into the annular space 33 formed between the receiving portion of the end connector and the retaining sleeve. One or more small openings may be provided in the securing collar for the purpose of injecting glue into the annular cavity 33. The injected adhesive performs two functions, firstly the adhesive forms a seal between the conduit and the end connector. Secondly, the adhesive forms both an adhesive bond and a mechanical bond anchoring the conduit and spine to the end connector. The mechanical bond is formed between the raised external threads of the end connector and the cured glue which fills the annular space between the end connector and the retaining sleeve. The mechanical bond between the raised threaded portion of the end connector and the breathing conduit is an important feature because there is no adhesive between these two surfaces. The cured glue must be hard enough to prevent the thin walled conduit and reinforcing bead from deforming enough to allow the conduit to be pulled over the raised external thread.

An alternative preferred embodiment of an end connector according to the present invention will now be described with reference to Figure 10. An end connector as described previously with an external raised thread 28 on a conduit receiving portion of

the connector is provided. In a similar manner to that described above the end connector is also provided with a recess 26 for receiving a reinforcing spine. During assembly the reinforcing spine is located in the recess before the helically ribbed breathing conduit is threaded over the reinforcing spine and receiving portion of the end connector. As described above, an end portion of the reinforcing spine 36 is folded over the outside of the breathing conduit wall in preparation for adhesive securing. The assembly is then inserted into a injection mould cavity so that a collar 38 (shown hatched) may be overmoulded to perform the functions of securing and sealing as described above.

Due to the axial compliance of very thin walled conduits, the length of spine will contribute to the determination of the length of the limb. In the preferred embodiment the spine length is chosen such that when fitted inside the conduit and secured to the respective end connectors, the conduit is elongated such that the conduit length is close to its maximum length (within the elastic limit of the walls). In such a condition the wrinkling of the conduit wall is reduced, improving the performance of the breathing circuit limb without putting undue stress on the conduit wall due to axial tension generated by the spine. The axial stiffness of the conduit is improved while limb flexibility is not significantly impaired.

A second preferred embodiment of the present invention will now be described in detail with reference to Figure 11. Figure 11 discloses a breathing circuit limb including an outer reinforcing sheath 27 covering the entire length of the breathing conduit.

The reinforcing sheath 27 is a braided mesh surrounding the breathing circuit limb and is bonded to the limb only at the ends where the breathing conduit is inserted into the end connectors. Both styles of breathing circuit limb end connectors described above are suitable for receiving and securing a reinforcing mesh according to the second embodiment of the present invention. In each case the reinforcing sheath is located outside the breathing conduit wall and is secured to the end connector at the same time as the conduit wall is secured. Figure 11 shows an end connector having a breathing conduit receiving portion which includes a raised external thread for cooperation with the helical

reinforcing bead of the conduit. The end connector may also include a recess or groove for receiving a reinforcing spine as described in the first preferred embodiment of the present invention. During assembly the thin walled breathing conduit is threaded over the end connector conduit receiving portion via the interaction between the breathing conduits helical reinforcing bead and the end connectors raised external thread. A tubular braided reinforcing mesh 27 is then installed over top of the breathing conduit. Figure 11 shows a reinforcing mesh 27 over a portion of breathing conduit. Note: The end portion of the mesh is not yet pulled all the way over the conduit ready for securing via retaining collar 29.

As previously described in the first preferred embodiment of the present invention there are disclosed two methods of securing the breathing circuit limb components. The first method employs a securing collar positioned over the breathing conduit and the conduit receiving portion of the end connector, forming an annular space which is then filled with a suitable adhesive such as EVA glue. The alternative securing method described in the first preferred embodiment of the present invention may be adapted to secure the braided reinforcing sheath into the end connector. In this overmoulded alternative the assembled components are inserted into an injection mould cavity so that a collar may be overmoulded to perform the functions of securing and sealing the components of the breathing circuit limb. In this method the retaining sleeve is substituted for the overmoulded resin.

The braided reinforcing mesh may be applied to a breathing conduit as an online process where the braid is formed at the same time as the conduit is formed, or alternatively a prebraided tube may be applied to a breathing conduit in a separate process. The braided mesh may be fabricated from a variety of materials but is preferably polyethylene terephthalate monofilament.

In use the braided sheath contributes significantly to the tensile and torsional stiffness of the breathing circuit limb. While there is no bonding between the reinforcing mesh and the breathing circuit limb along the length of the conduit is has been found that

the braided reinforcing mesh significantly improves the breathing circuit limbs torsional rigidity. In this embodiment it is preferable to choose the material, number, weave pitch and gauge of the braided filaments to improve the conduits stiffness. When the limb is loaded in tension, the stretching of the reinforcing mesh causes the mesh tube to constrict radially. This radial constriction is resisted by the helical reinforcing bead of the breathing conduit resulting in a strain limiting effect for the breathing circuit limb. This effect significantly improves the breathing circuit limbs strength and stiffness against axial tensile forces. The outer mesh sheath also provides an additional advantage by reducing direct contact between the user/environment and the outer surface of the breathing conduit tube, therefore reducing the risk of puncture and damage. This feature significantly improves the durability of the breathing circuit limb, especially where very thin walls such as those which may be found in breathable walled limbs.

DATED THIS 9th DAY OF September 2002

AJ PARK

AGENTS FOR THE APPLICANT



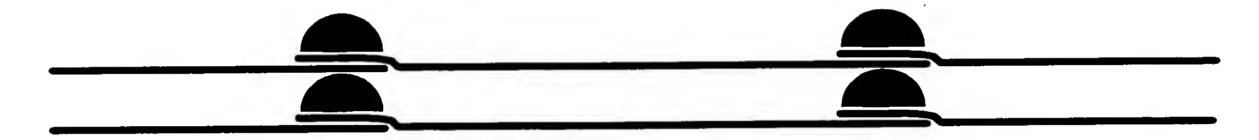


Figure 2

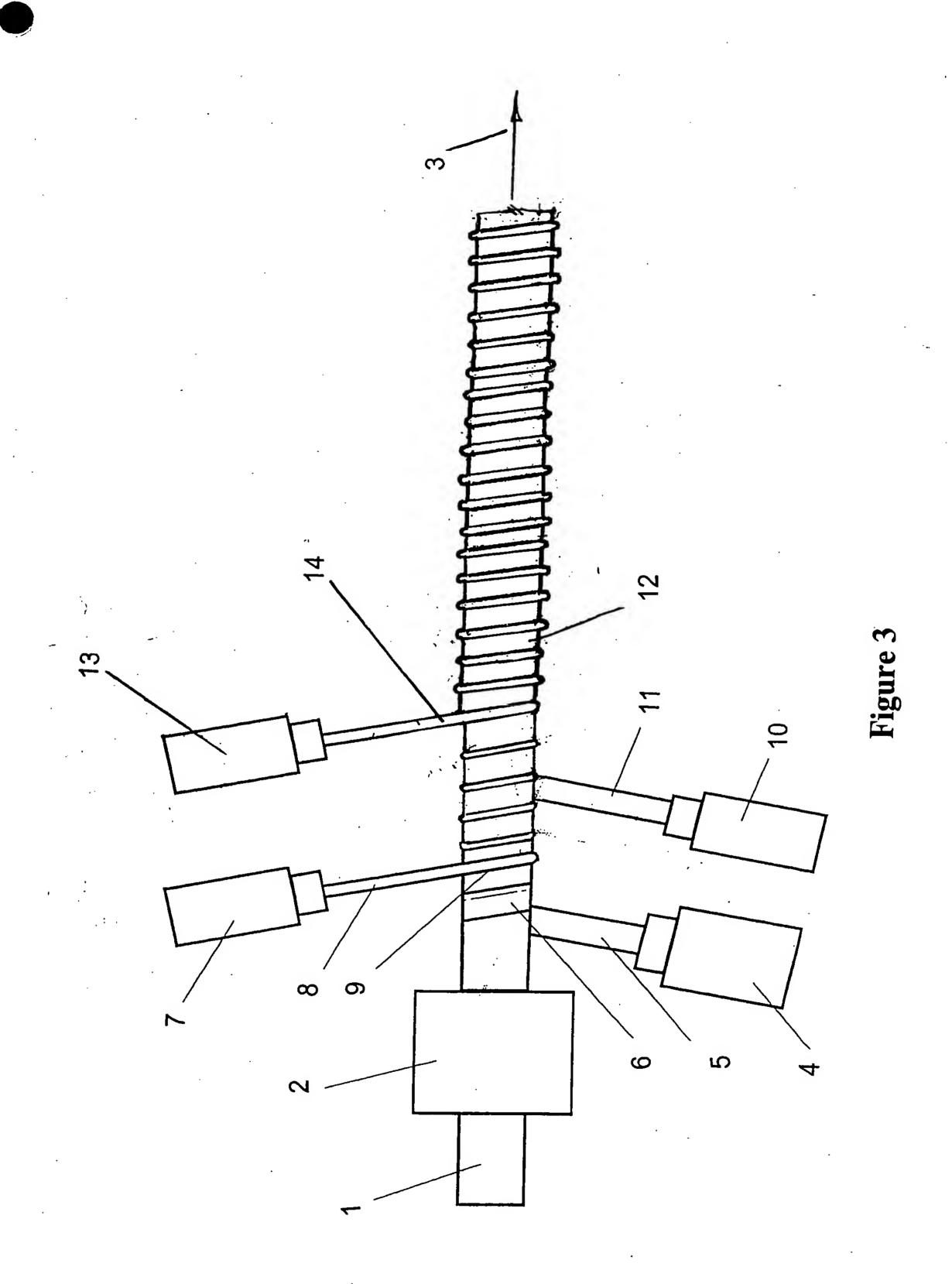
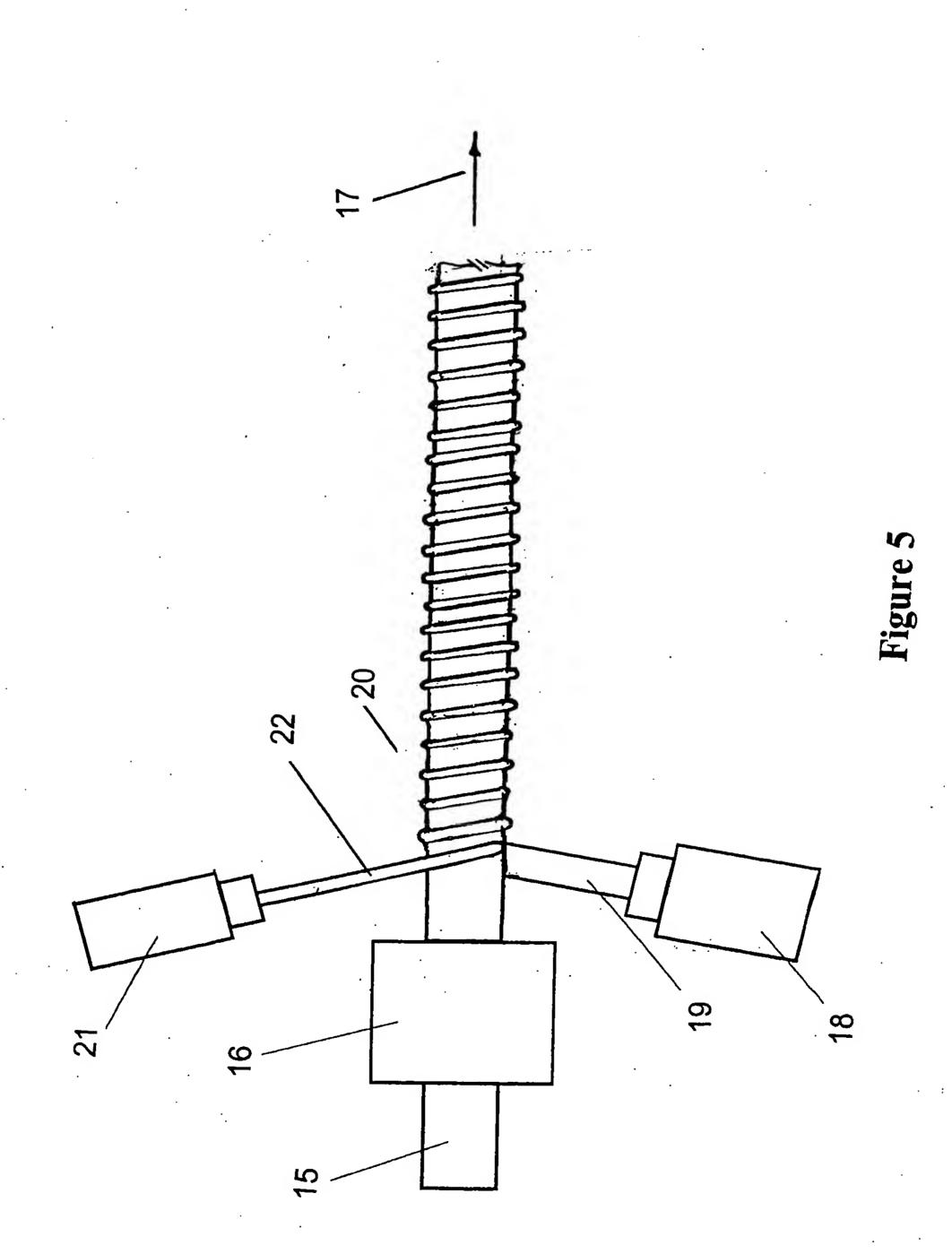


Figure 4



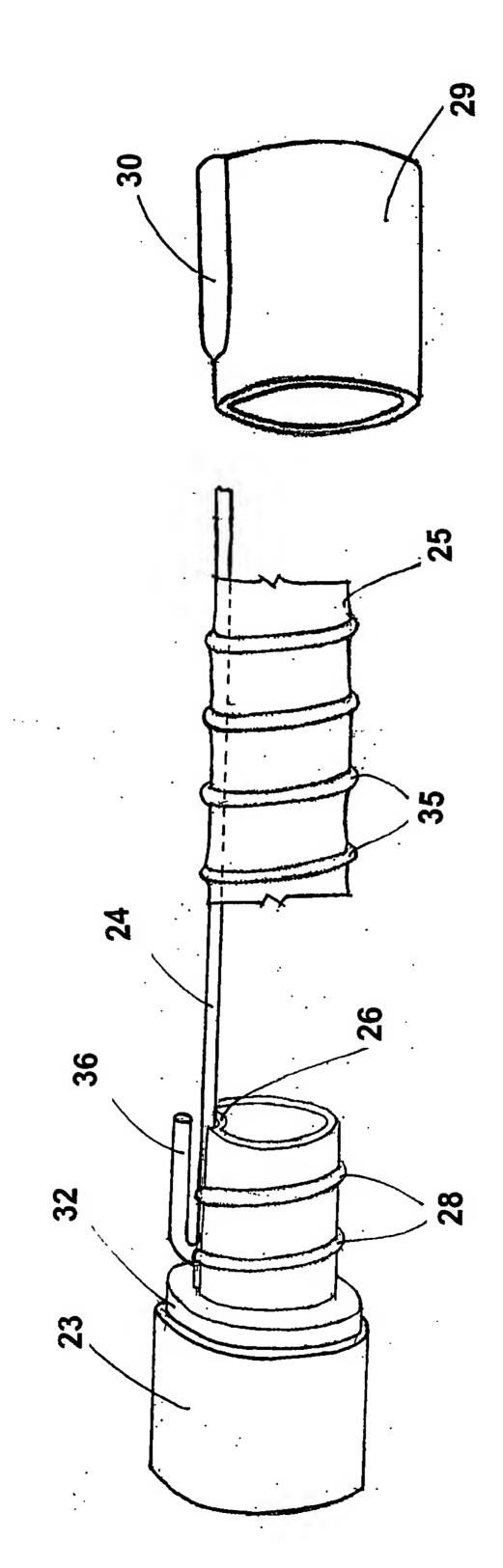


Figure 6

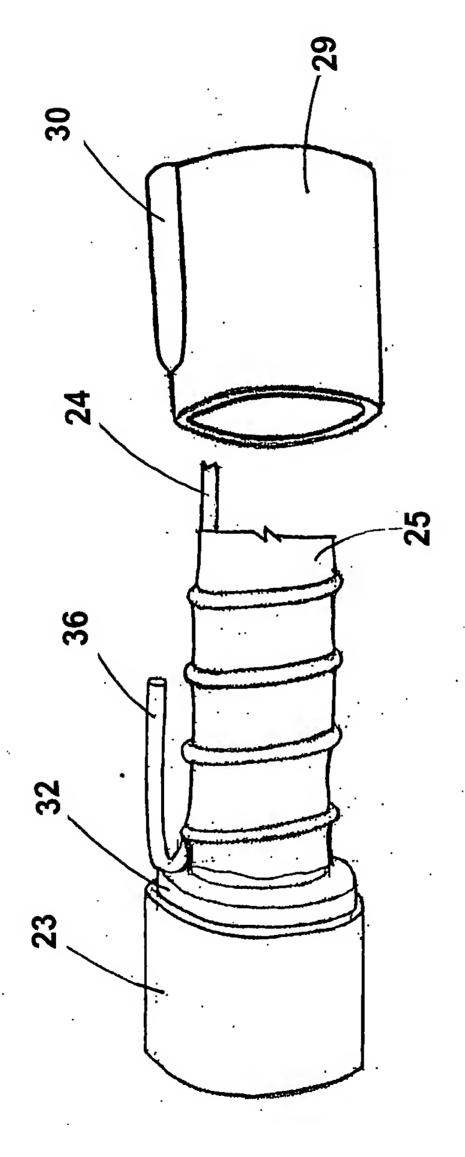


Figure 7

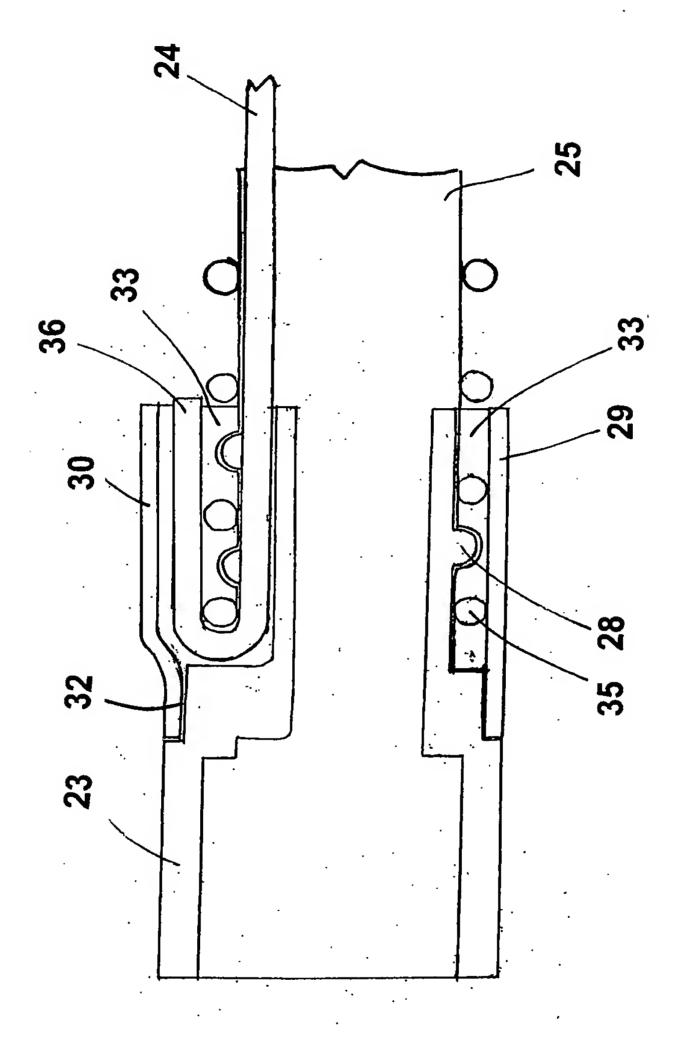


Figure 8

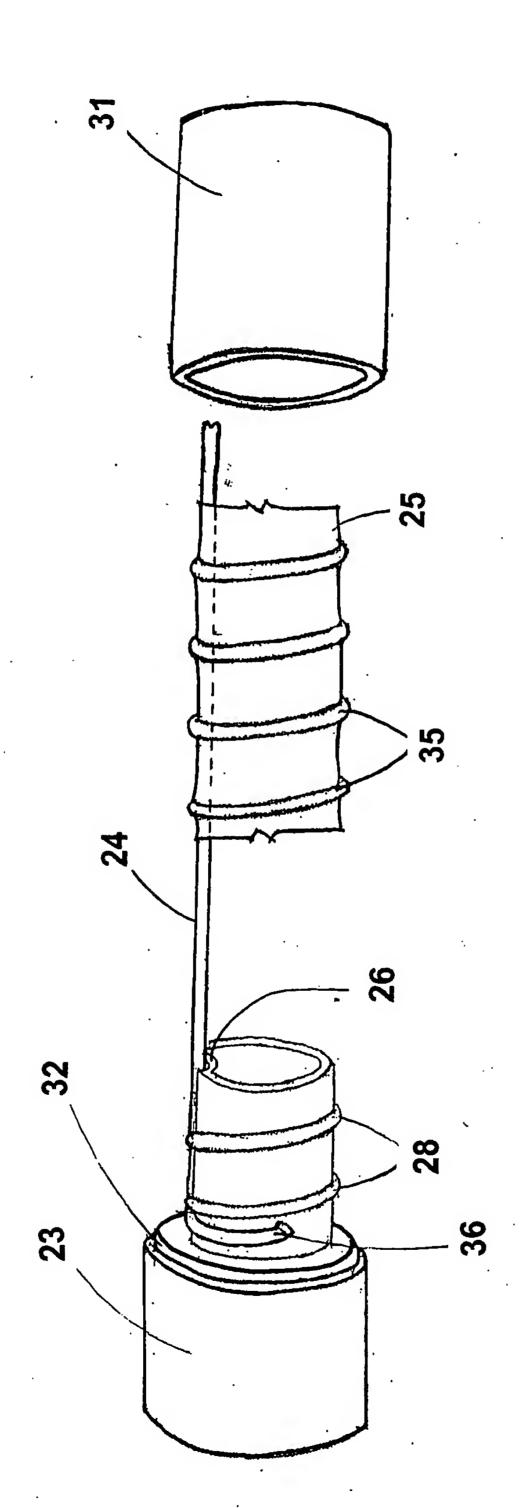
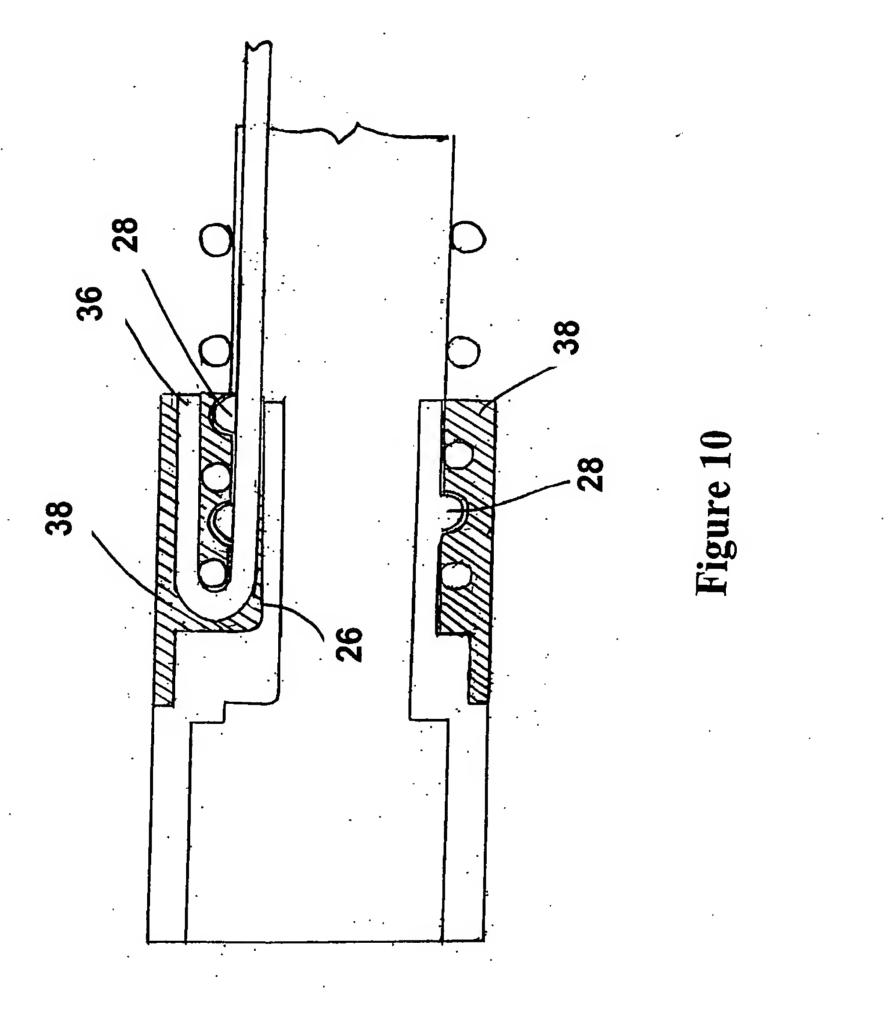


Figure 9



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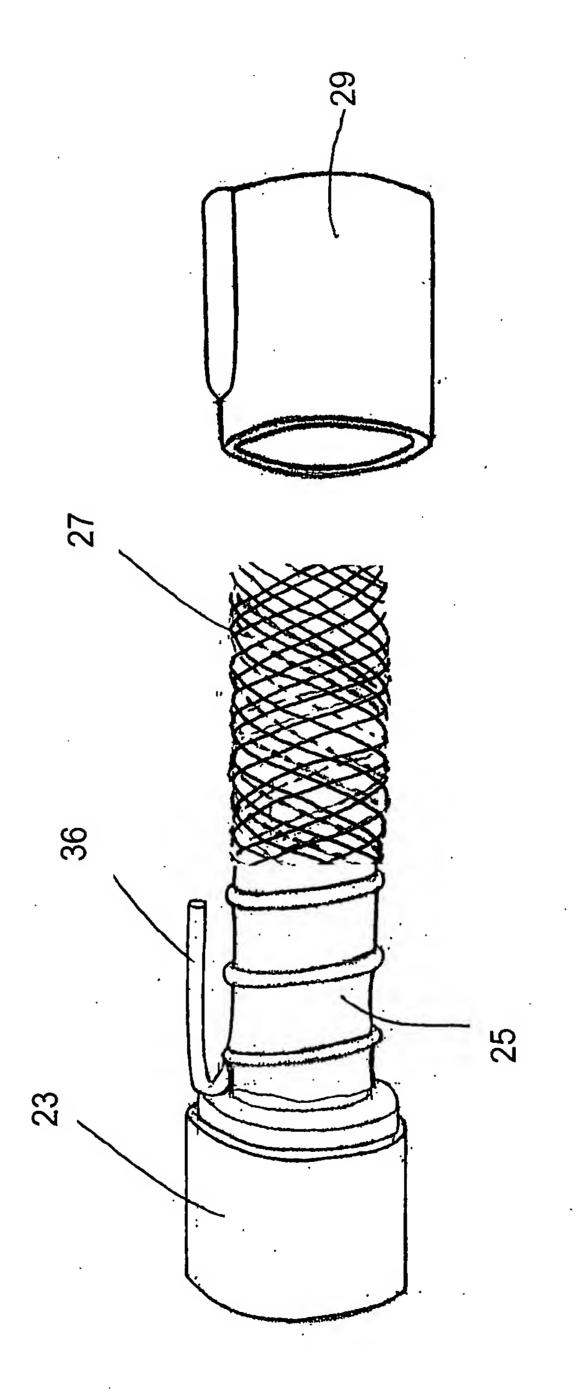


Figure 11